

Urgent !

Field Safety Notice (FSN)

GETINGE 

Version
(Version)

V 01

Gültig ab
(valid from)

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Page 1 of 4

2019-05-10

FSCA Number: FSCA-2019-05-06

FSCA Title: Potential leakage at QUADROX-i Neonatal blood inlet connector

Affected Product:

- All variants and sets of QUADROX-i Neonatal which include the reducing screw adapter 1/4" x 3/16" (Ref.No. 70104.8593)
- All Custom Tubing Sets which contain a pre-connected reducing screw adapter 1/4" x 3/16" (Ref.No. 70104.5511) at the blood inlet connector of the QUADROX-i Neonatal Oxygenator

Affected product details:

See attached Annex I

Description of the problem: Dear valued customers,

All variants and sets of QUADROX-i Neonatal Oxygenators are supplied with a separate reducing screw adapter 1/4" x 3/16". It can be screwed onto the blood inlet and blood outlet connectors of the QUADROX-i Neonatal Oxygenator to reduce the port to size 3/16".

Customized Tubing Sets that contain the QUADROX-i Neonatal Oxygenators in combination with a pre-connected reducing screw adapter 1/4" x 3/16" on the blood inlet connector of the oxygenator are also covered by this FSN.

Maquet Cardiopulmonary has received complaints in relation to leakage at the QUADROX-i Neonatal blood inlet connector.

Internal investigations have revealed that the leakage only occurs if the enclosed reducing screw adapter 1/4" x 3/16" is screwed onto the blood inlet connector of the QUADROX-i Neonatal Oxygenator. The leakage occurs due to a non-conforming blood inlet connector that, in conjunction with the use of the screw reducing adapter 1/4" x 3/16", does not result in a tight connector-adapter connection. The combination of the reducing screw adapter 1/4" x 3/16" with the blood outlet connector or the use of the blood inlet connector directly to tubing does not exhibit any leakage.

Governing Procedure: SV 09.11

FB-0087b

Version: 04

Gültig ab: 2018-09-18

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Gültig ab: 2018-06-25

Governing Procedure: SV 02.03

Urgent !
Field Safety Notice (FSN)



Version
(Version)
V 01

Gültig ab
(valid from)
See last signature

Page 2 of 4

Using the QUADROX-i Neonatal Oxygenator in conjunction with the reducing screw adapter 1/4" x 3/16" can result in clinically relevant loss of prime before patient connection or blood loss during patient connection. Clinicians need to judge whether or not to replace the device, but device replacement is the mitigation of choice if leakage exceeds the clinically acceptable limit. Risks associated with device replacement during patient connection include but are not limited to interruption of cardiopulmonary bypass, blood loss and infection.

Maquet Cardiopulmonary thus recommends not using the adapter at the blood inlet connector of the QUADROX-i Neonatal Oxygenator. We also recommend to return any Customized Tubing Sets with a screw reducing adapter pre-attached to the blood inlet connector to Maquet Cardiopulmonary. If the use of the products is medically necessary, remove the pre-connected screw reducing adapter at the blood inlet connector of the customized tubing set and following the further instructions for an alternative method of tubing reduction below.

Using the device without the reducing screw adapter at all or using an alternative method of tubing reduction (see below) safely allows operators to set up and operate cardiopulmonary bypass without the potential necessity of device replacement in case of leakage. Maquet's recommendation outweighs the risks associated with device use with the reducing screw adapter.

Maquet Cardiopulmonary has not received any complaints associated to serious injuries or deaths due to a leakage at the blood inlet connector.

Should you wish to reduce the blood inlet port to 3/16", we recommend connecting 1/4" tubing to the inlet of the QUADROX-i Neonatal Oxygenator, reducing the 1/4" tubing to 3/16" using a standard tubing reducer. Two tie bands should be placed on all connections with the tie band heads oriented in a 180 degree configuration as shown below.



Urgent !

Field Safety Notice (FSN)

GETINGE 

Version
(Version)

V 01

Gültig ab
(valid from)

See last signature

Page 3 of 4

**Corrective
Action:**

For Customized Tubing Sets with a pre-connected reducing screw adapter on the blood inlet connector of the oxygenator:

- Return to your local Getinge representative any unused Customized Tubing Set with a pre-connected reducing screw adapter on the blood inlet connector of the oxygenator
- If medical necessary to use these Customized Tubing Sets, remove and do not use the **pre-connected** reducing screw adapter 1/4" x 3/16" (Ref. No. 70104.5511). Follow the further instructions to reduce the tubing using a standard tubing reducer.

For Tubing Sets with a reducing screw adapter packaged separately:

- Remove and do not use the **enclosed** reducing screw adapter 1/4" x 3/16" (Ref. No. 70104.8593)
- In case you also do not want to use this product with a standard tubing reducer, please return the product to your local Getinge representative

**Advice on action
to be taken by the
user:**

- **Based on above, no removal of the product is generally required.**
- The scope of this FSN encompasses all Maquet Cardiopulmonary GmbH (MCP) products containing the QUADROX-i Neonatal Oxygenator and the reducing screw adapter 1/4" x 3/16" (Ref. No. 70104.8593) and all Custom Tubing Sets which contain a pre-connected reducing screw adapter 1/4" x 3/16" (Ref.No. 70104.5511) at the blood inlet connector of the QUADROX-i Neonatal Oxygenator.
- Return any unused affected product to your local Getinge representative.
- According to our surveillance documentation, your current stock may include products affected by this action.
- Please fill and sign the attached Letter of Acknowledgement for customer and send it back to your local Getinge representative.

**Referenced
documents/
attachments:**

- Annex I: List of affected products
- Letter of Acknowledgement Customer

Governing Procedure: SV 09.11

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Urgent !
Field Safety Notice (FSN)



Version
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See last signature

Transmission of the Field Safety Notice:

- This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.
- Please transfer this notice to other organizations on which the action has an impact.
- Please maintain awareness on the notice and resulting actions for an appropriate period to ensure effectiveness of the corrective action.

We apologize for any inconvenience this may cause you and we will do our utmost to carry through this action as swiftly as possible.

As required, we have provided this notification to the necessary Regulatory Agencies.

Should you have questions or require additional information, please contact your local Maquet representative

Managing Director

2019-05-10

Timothy J. Talcott
(Senior Director of
Quality Improvement
Programs)

UTC 2019-05-10,
11:33:33

Signatory:
Nursel Boelens (Director of
Regulatory Affairs)

Signature / Unterschrift

Safety Officer

Maquet Cardiopulmonary GmbH
Kehler Str. 31
76437 Rastatt
GERMANY

Urgent!

Field Safety Notice (FSN)

-Annex I-

List of affected products country-/ region-specific



This Annex I is considered as a supplementary attachment to the Field Safety Notice of FSCA-2019-05-06

FSCA Number: FSCA-2019-05-06

FSCA Title: Potential leakage at QUADROX-i Neonatal blood inlet connector

Affected Products:

- All variants and sets of QUADROX-i Neonatal which include the reducing screw adapter 1/4" x 3/16" (Ref.No. 70104.8593)
- All Custom Tubing Sets which contain a pre-connected reducing screw adapter 1/4" x 3/16" (Ref.No. 70104.5511) at the blood inlet connector of the QUADROX-i Neonatal Oxygenator

Affected Timeframe: Products manufactured between October 2018 – April 2019

List of affected products				
Country	Material No.	Material Description	Lot No.	Qty.
Brazil	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92261622	100
Brazil	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92261625	100
Canada	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92261619	5
Canada	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92261621	10
Canada	701050109	VKMO 10000#QUADROX-i Neo. mit Reservoir	92254562	23
Canada	701053444	BO-VKMO 11000#QUADROX-i Neo.+BO Reserv.	92250690	22
Canada	701053444	BO-VKMO 11000#QUADROX-i Neo.+BO Reserv.	92250690	16
Canada	701053444	BO-VKMO 11000#QUADROX-i Neo.+BO Reserv.	92250693	10
Canada	701053444	BO-VKMO 11000#QUADROX-i Neo.+BO Reserv.	92250693	30
Canada	701053444	BO-VKMO 11000#QUADROX-i Neo.+BO Reserv.	92250693	8
Canada	701053444	BO-VKMO 11000#QUADROX-i Neo.+BO Reserv.	92250695	20

Urgent!

Field Safety Notice (FSN)



-Annex I-

List of affected products country-/ region-specific

Canada	701054973	BO-HQV 48412#Custom HMO 11000 + BO-VHK 3	92245472	6
Canada	701054973	BO-HQV 48412#Custom HMO 11000 + BO-VHK 3	92245632	6
Canada	701054973	BO-HQV 48412#Custom HMO 11000 + BO-VHK 3	92253762	6
Canada	701054973	BO-HQV 48412#Custom HMO 11000 + BO-VHK 3	92253763	6
Canada	701054973	BO-HQV 48412#Custom HMO 11000 + BO-VHK 3	92254281	3
Canada	701054973	BO-HQV 48412#Custom HMO 11000 + BO-VHK 3	92254281	3
Canada	701054973	BO-HQV 48412#Custom HMO 11000 + BO-VHK 3	92255751	1
Canada	701054973	BO-HQV 48412#Custom HMO 11000 + BO-VHK 3	92255751	3
Canada	701054973	BO-HQV 48412#Custom HMO 11000 + BO-VHK 3	92256130	6
Canada	701054973	BO-HQV 48412#Custom HMO 11000 + BO-VHK 3	92256131	4
Canada	701054973	BO-HQV 48412#Custom HMO 11000 + BO-VHK 3	92262912	3
Canada	701054973	BO-HQV 48412#Custom HMO 11000 + BO-VHK 3	92263959	2
China	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92260974	2
China	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92260977	1
China	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92260978	73
China	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92260979	50
China	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92261619	102
China	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92261620	200
China	701050109	VKMO 10000#QUADROX-i Neo. mit Reservoir	92260983	100
Colombia	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92260978	10
Colombia	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92260979	32

Urgent!

Field Safety Notice (FSN)

-Annex I-

List of affected products country-/ region-specific



France	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92258898	6
France	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92258898	6
France	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92258898	10
France	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92258898	10
France	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92258898	20
France	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92260974	6
France	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92260974	10
France	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92261619	14
France	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92261621	4
Germany	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92258898	10
Germany	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92258898	20
Germany	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92258898	20
Germany	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92258898	10
Germany	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92260974	10
Germany	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92260977	1
Germany	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92260977	12
Germany	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92260977	20
Germany	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92260977	11
Germany	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92260977	10
Germany	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92260978	8
Germany	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92261619	13

Urgent!

Field Safety Notice (FSN)

-Annex I-

List of affected products country-/ region-specific



Germany	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92261619	9
Germany	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92261620	20
Germany	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92261621	4
Germany	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92261622	10
Germany	701073392	HQV 0613u#HLM-Set 3/16x1/4	92265783	1
India	701050109	VKMO 10000#QUADROX-i Neo. mit Reservoir	92254562	34
Ireland	701067343	HQV 85503#Minuaturised Neonatal Pack w/o	92245286	5
Ireland	701067343	HQV 85503#Minuaturised Neonatal Pack w/o	92245286	2
Ireland	701067343	HQV 85503#Minuaturised Neonatal Pack w/o	92245287	3
Ireland	701067343	HQV 85503#Minuaturised Neonatal Pack w/o	92245287	2
Ireland	701067343	HQV 85503#Minuaturised Neonatal Pack w/o	92245287	2
Ireland	701067343	HQV 85503#Minuaturised Neonatal Pack w/o	92245553	3
Ireland	701067343	HQV 85503#Minuaturised Neonatal Pack w/o	92245553	3
Ireland	701067343	HQV 85503#Minuaturised Neonatal Pack w/o	92245553	1
Ireland	701067343	HQV 85503#Minuaturised Neonatal Pack w/o	92249506	3
Ireland	701067343	HQV 85503#Minuaturised Neonatal Pack w/o	92249506	1
Ireland	701067343	HQV 85503#Minuaturised Neonatal Pack w/o	92253560	1
Italy	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92258898	4
Italy	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92260974	4
Italy	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92260974	4
Italy	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92260977	3

Urgent!

Field Safety Notice (FSN)



-Annex I-

List of affected products country-/ region-specific

Italy	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92261619	1
Italy	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92261622	4
Italy	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92261622	1
Japan	701063696	HMO 11000-J#QUADROX-i neo.m.Filt.micr.So	70126910	20
Japan	701063696	HMO 11000-J#QUADROX-i neo.m.Filt.micr.So	70126910	40
Japan	701063696	HMO 11000-J#QUADROX-i neo.m.Filt.micr.So	70128648	40
Mexico	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92260974	2
Mexico	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92261624	10
Mexico	701053444	BO-VKMO 11000#QUADROX-i Neo.+BO Reserv.	92250690	4
Poland	701050109	VKMO 10000#QUADROX-i Neo. mit Reservoir	92255877	10
Poland	701050109	VKMO 10000#QUADROX-i Neo. mit Reservoir	92260983	40
Russia	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92260977	5
Russia	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92260977	30
Russia	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92261622	20
Serbia	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92260974	25
Serbia	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92260978	5
Serbia	701050109	VKMO 10000#QUADROX-i Neo. mit Reservoir	92255877	20
South Africa	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92258898	20
South Africa	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92260974	20
South Korea	701050109	VKMO 10000#QUADROX-i Neo. mit Reservoir	92254562	30

Urgent!

Field Safety Notice (FSN)



-Annex I-

List of affected products country-/ region-specific

South Korea	701050109	VKMO 10000#QUADROX-i Neo. mit Reservoir	92254562	5
South Korea	701050109	VKMO 10000#QUADROX-i Neo. mit Reservoir	92254562	30
South Korea	701050109	VKMO 10000#QUADROX-i Neo. mit Reservoir	92254562	5
South Korea	701050109	VKMO 10000#QUADROX-i Neo. mit Reservoir	92255877	2
South Korea	701050109	VKMO 10000#QUADROX-i Neo. mit Reservoir	92255877	5
Spain	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92258898	4
Spain	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92258898	4
Spain	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92260974	5
Spain	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92261621	8
Spain	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92261621	1
Spain	701050109	VKMO 10000#QUADROX-i Neo. mit Reservoir	92261633	3
Switzerland	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92261621	4
Taiwan	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92260974	10
Turkey	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92261621	30
UK	701049158	HQV 51203#Neonatal Tubing Set	92245566	14
UK	701049158	HQV 51203#Neonatal Tubing Set	92254487	7
UK	701049158	HQV 51203#Neonatal Tubing Set	92254487	7
UK	701049158	HQV 51203#Neonatal Tubing Set	92262172	8

Urgent!

Field Safety Notice (FSN)

-Annex I-

List of affected products country-/ region-specific



UK	701049158	HQV 51203#Neonatal Tubing Set	92266772	12
UK	701049158	HQV 51203#Neonatal Tubing Set	92267206	13
UK	701049158	HQV 51203#Neonatal Tubing Set	92272110	3
UK	701049158	HQV 51203#Neonatal Tubing Set	92272110	10
UK	701049158	HQV 51203#Neonatal Tubing Set	92272110	1
UK	701049158	HQV 51203#Neonatal Tubing Set	92272301	3
UK	701049158	HQV 51203#Neonatal Tubing Set	92272301	9
UK	701049158	HQV 51203#Neonatal Tubing Set	92272396	4
UK	701049158	HQV 51203#Neonatal Tubing Set	92272396	3
UK	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92260974	3
UK	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92260974	27
UK	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92260977	3
UK	701049279	VKMO 11000#QUADROX-i Neo. mit Reservoir	92261620	20
UK	701050109	VKMO 10000#QUADROX-i Neo. mit Reservoir	92255877	11
UK	701050109	VKMO 10000#QUADROX-i Neo. mit Reservoir	92260983	1
UK	701071777	HQV 86303#Neonatal Pack	92245505	4
UK	701071777	HQV 86303#Neonatal Pack	92245505	1
UK	701071777	HQV 86303#Neonatal Pack	92245505	5
UK	701071777	HQV 86303#Neonatal Pack	92245505	4
UK	701071777	HQV 86303#Neonatal Pack	92245505	3
UK	701071777	HQV 86303#Neonatal Pack	92245505	5

Urgent!

Field Safety Notice (FSN)

-Annex I-

List of affected products country-/ region-specific



UK	701071777	HQV 86303#Neonatal Pack	92245505	8
UK	701071777	HQV 86303#Neonatal Pack	92245641	4
UK	701071777	HQV 86303#Neonatal Pack	92245641	1
UK	701071777	HQV 86303#Neonatal Pack	92245641	5

Please note: SSUs are called to actively find out whether the listed devices have been forwarded or sold into any other country. That country where the unit is currently located is also an affected country. Please send any information about forwarding and selling to other countries to: FSCA.cp@getinge.com.

We apologize for any inconvenience this may cause you and we will do our utmost to carry through this action as swiftly as possible.

For follow up actions, please contact us on FSCA.cp@getinge.com.

Sincerely,

Maquet Cardiopulmonary GmbH

Kehler Str. 31

76437 Rastatt

GERMANY